

SECTION V REPORT ON CARCINOGENS LISTING/DELISTING PROCEDURES

Nominations for listing or delisting an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) should be submitted to the National Toxicology Program (NTP)¹. Nominations must contain a rationale for listing or delisting as either a “known human carcinogen” or a “reasonably anticipated human carcinogen”. Appropriate background information and relevant data (e.g., journal articles, NTP Technical Reports, IARC listings, exposure surveys, release inventories, etc.) which support a nomination should be provided or referenced when possible.

An agent, substance, mixture, or exposure circumstance nominated for listing or delisting will be evaluated initially by a National Institute of Environmental Health Sciences (NIEHS/NTP) RoC Review Committee (RG1), composed of scientists from the NIEHS/NTP, to determine if the information provided is sufficient to merit further consideration. If it is determined that the nomination contains insufficient information to warrant consideration by the NTP, it will be returned to the original nominator who will be invited to resubmit the nomination with additional justification, which may include new data, exposure information, etc. This decision will also be forwarded to the NTP Executive Committee² and the NTP Board of Scientific Counselors.

If it is determined the nomination warrants formal consideration, it will be announced in the *Federal Register*, trade journals, and NTP publications to solicit public comment. The NTP may initiate an independent search of the literature and have a draft background document prepared for the nomination under consideration. NTP RoC background documents will be prepared according to the following general format:

1.0 Introduction

1.1 Chemical identification

synonyms, trade names, CAS Nos., molecular formula, molecular structure, etc.

1.2 Physical-chemical properties

1.3 Identification of structural analogs or metabolites

2.0 Human Exposure

2.1 Use

2.2 Production

2.3 Analysis

2.4 Environmental occurrence

environmental release, drinking water and food content, consumer products

2.5 Environmental fate

environmental fate in air, water, and soil

2.6 Environmental exposure

2.7 Occupational exposure

2.8 Biological indices of exposure

2.9 Regulations

occupational exposure limits (standards and criteria), other standards and criteria

3.0 Human Studies

4.0 Experimental Carcinogenesis

5.0 Genotoxicity

6.0 Other Data Relevant to Evaluation of Carcinogenicity and its Mechanisms

Data used in the preparation of Sections 3 through 6 of the draft document must come from publicly available, peer-reviewed sources.

FORMAL REVIEW STEPS

The following describes the review process for nominations that are considered by the NTP for listing in or delisting from the Report on Carcinogens:

NIEHS/NTP RoC Review Committee (RG1)

The original nomination will be reviewed by RG1. Primary reviewers for each nomination will be assigned from the RG1 and will be responsible for reviewing the background document in detail and leading the RG1's discussion of the nomination. Public comments received in response to announcements of the nomination will be reviewed by the RG1. After an initial review by the RG1, the background document will be revised, if necessary, for the final review and recommendation for listing or delisting by the RG1. The nomination then continues through the review process.

Nominations reviewed by RG1 for which sufficient information could not be obtained for applying the criteria for listing or delisting in the RoC will not proceed further in the review process. The subsequent RoC review groups, as well as the NTP Executive Committee, will be informed of this action and will have access to the information pertaining to the reasons why the nomination will not proceed further. The original nominator will be notified of the RG1 action and will be invited to resubmit the nomination with additional justification. All nominations reviewed by RG1 for which there was insufficient information to apply the criteria for listing or delisting in the RoC will be identified in the subsequent edition of the RoC with the reason(s) why they were not considered further .

NTP Executive Committee's Interagency Working Group for the RoC (RG2)

The second review of a nomination is by the NTP Executive Committee's Interagency Working Group for the RoC. RG2 is a governmental interagency scientific review group that assesses whether relevant information for the nomination is available and sufficient for listing in or delisting from the RoC. Primary reviewers for each nomination will be assigned from the RG2 and will be responsible for reviewing the background document in detail and leading the RG2's discussion of the nomination. Public comments received in response to announcements of nominations will also be addressed by RG2 during the review. Upon completion of its review, RG2 will provide comments and make its recommendations for listing or delisting the nominations in the RoC.

Board of Scientific Counselors RoC Subcommittee (External Peer Review)

External peer review will be performed by a subcommittee of the NTP Board of Scientific Counselors. This subcommittee serves as an independent peer review group that assesses whether the relevant information available is sufficient for listing or delisting in the RoC. The subcommittee will review nominations in an open public meeting. Prior to public review, a notice will be published in the *Federal Register*, trade journals, and NTP publications, soliciting public comment. The notice will also invite interested groups or individuals to submit written comments and/or to address the subcommittee during the public review meeting. Primary reviewers for each nomination will be assigned from the subcommittee and will be responsible for reviewing the background document in detail and leading the subcommittee's discussion of the nomination. Upon completion of its review, the subcommittee will provide comments and make its recommendations for listing or delisting the nominations in the RoC.

Public Comment

Upon completion of the reviews by RG1, RG2, and the Board subcommittee, those nominations recommended for listing in, delisting from, or not to list in the RoC will be published in the *Federal Register*, trade journals, and NTP publications; and final public comment and input on the recommendations will be solicited.

NTP Executive Committee

The recommendations of RG1, RG2, and Board subcommittee, and all public comments received will be presented to the NTP Executive Committee² for review and comment.

NTP Director

The Director, NTP, reviews all recommendations and makes final decisions regarding the proposed listing and/or delisting and submits the final draft of the RoC to the Office of the Secretary, Department of Health and Human Services (DHHS). The Director, NTP receives the three independent recommendations for the nominations from RG1, RG2, and the NTP Board RoC Subcommittee, and the opinion of the NTP Executive Committee concerning these recommendations. Based on this input and his/her evaluation of the relevant information, the

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Director makes his/her final recommendation of which nominations should be listed in or delisted from the latest edition of the draft RoC and submits it to the Secretary, DHHS.

Secretary, Department of Health and Human Services (DHHS)

The final draft of the RoC is submitted by the Director, NTP to the Secretary, DHHS for review and final approval. Upon approval of the RoC, the Secretary submits it to the U.S. Congress as a final document. The submission of the RoC to Congress constitutes publication of the RoC and the report becomes available to the public at that time. A notice of the publication and availability of the latest edition of the RoC, indicating all newly listed or delisted agents, substances, mixtures, or exposure circumstances will be published in the *Federal Register*, trade journals, and NTP newsletter publications.

¹ National Toxicology Program, Report on Carcinogens,
P.O. Box 12233, 79 Alexander Drive, Bldg. 4401,
Room 3118, MD-EC-14, Research Triangle Park, NC 27709
For information contact: Dr. C. W. Jameson, phone: (919) 541-4096,
fax: (919) 541-0144, e-mail: jameson@niehs.nih.gov

² Agencies represented on the NTP Executive Committee include:
Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), National Center for Environmental Health of the Centers for Disease Control and Prevention (NCEH/CDC), National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA), National Institute for Occupational Safety and Health/CDC (NIOSH/CDC), Occupational Safety and Health Administration (OSHA), National Cancer Institute of the National Institutes of Health (NCI/NIH), and National Institute of Environmental Health Sciences/NIH (NIEHS/NIH)